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DATE MAILED: 11/21/2006

| APPLICATION NO.        | FII                              | LING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|------------------------|----------------------------------|------------|----------------------|---------------------|-----------------|
| 09/463,801             | 07/28/2000                       |            | Holger Lowe          | 678-99              | 6812            |
| 27569                  | 7590                             | 11/21/2006 |                      | EXAMINER            |                 |
| PAUL AN                |                                  |            | STULII, VERA         |                     |                 |
|                        | 2000 MARKET STREET<br>SUITE 2900 |            |                      | ART UNIT            | PAPER NUMBER    |
| PHILADELPHIA, PA 19103 |                                  |            |                      | 1761                |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)   |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|
|   | 09/463,801  | LOWE ET AL.  |  |  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |  |  |
|   | Vera Stulii   | 1761   |  |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c  | orrespondence address  |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY  | IS SET TO EXPIRE 3 MONTH(   | S) OR THIRTY (30) DAYS.  |  |  |  |  |  |  |
| <ul> <li>WHICHEVER IS LONGER, FROM THE MAILING DA</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period w</li> <li>Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul> | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim iiii apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. sely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |  |  |
| Status  |   | •  |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 18 Au  | <u>igust 2006</u> .   |  |  |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |  |  |  |
| •   | -   |  |  |  |  |  |  |  |
| closed in accordance with the practice under E  | x parte Quayle, 1935 C.D. 11, 45  | 53 O.G. 213.   |  |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |  |  |
| 4)⊠ Claim(s) 22-74 is/are pending in the application  | ١.  |  |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw   | 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |  |  |  |  |  |  |  |
| 6)⊠ Claim(s) <u>22-74</u> is/are rejected.  | 6)⊠ Claim(s) <u>22-74</u> is/are rejected.  |  |  |  |  |  |  |  |
|   | 7) Claim(s) is/are objected to.   |  |  |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o  | r election requirement.   |  |  |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examine   | r.  |  |  |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ acc  |   |  |  |  |  |  |  |  |
| Applicant may not request that any objection to the   |   |  |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correct  |   |  |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Ex  | aminer. Note the attached Oπice   | Action or form PTO-152.  |  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |  |  |  |  |  |  |
| 12)⊠ Acknowledgment is made of a claim for foreign<br>a)  All b)⊠ Some * c)  None of:   | priority under 35 U.S.C. § 119(a)   | )-(d) or (f).  |  |  |  |  |  |  |
|   | 1. Certified copies of the priority documents have been received.   |  |  |  |  |  |  |  |
| 2. Certified copies of the priority document  |   |  |  |  |  |  |  |  |
| 3. Copies of the certified copies of the prior  |   | ed in this National Stage  |  |  |  |  |  |  |
| application from the International Bureau  * See the attached detailed Office action for a list   |   | od.  |  |  |  |  |  |  |
| See the attached detailed Office action for a list  | or the defined copies not receive   |  |  |  |  |  |  |  |
| Attachment(s)   |   |  |  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   | 4) Interview Summary  |  |  |  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application   |   |  |  |  |  |  |  |  |
| Paper No(s)/Mail Date   | 6) Other:   |  |  |  |  |  |  |  |

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 30-31, \$\frac{31}{88}\$, 46, 59, 60 and \$\frac{60}{80}\$ are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

In claim 22 and 46, it is not clear what is meant by the word "treating".

In claim 30 and 59, it is not clear what is meant by "treatment" and "undesired". Claim 30 and 59 recite the limitation "the treatment" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is also not clear what exactly is "selected from the group consisting of microorganisms and active substances". The recitation of a selection from a group of elements in a claim should comply with accepted U.S. Patent practice with regard to the recitation of Markush grouping of claim elements. Phrases using "comprising" are open sets, and should recite elements in the alternative (i.e. "comprising A, B, C or D"), whereas closed sets ("consisting of") should recite elements as "selected from the group consisting of A, B, C and D. Regarding the use of "selected from the group consisting of" phrase within the instant claims where a

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number of whole elements are listed, it is unclear as to what may be included or excluded from the claim by this phrase.

In claims 30, 31, 59 and 60, it is not clear what is meant by "undesired".

In claims and regarding the use of the phrase "comprises at least one species of yeast used in wine production as well as at least one of a yeast cell wall preparation and a glucose-fructose-isomerases" within the instant claims where a number of whole elements are listed, it is unclear as to what may be included or excluded from the claim by this phrase. The recited format ("consisting essentially of" the recited possible elements) does not comply with accepted U.S. Patent practice with regard to the recitation of Markush grouping of claim elements. Phrases using "comprising" should recite elements in the alternative (i.e. "comprising A, B, C or D"), whereas closed sets ("consisting of") should recite elements as "selected from the group consisting of A, B, C and D."

## Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-23, 28-29 and 46, 52, 57, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Schrezenmeir et al (DE 19519804).

In regard to claims 22, 28-29 and 46, Schrezenmeir et al disclose "bioactive capsule for installation in a living tissue or for biotechnical use" (Abstract). Schrezenmeir et al disclose that "bioactive capsule has a core which contains living cell and/or

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enzymes and a multilayered sheath which completely encloses the core" (Abstract, Fig. 1). Schrezenmeir et al disclose that "the sheath consists of a porous mesh of flocculated micromolecules" (Abstract). Schrezenmeir et al disclose that the covering of capsule is mechanically stable (Translation p.1). Schrezenmeir et al disclose that "connection can be made between the core and outside" (Translation p.2). Schrezenmeir et al teach that the covering consists of several layers, which enclose the core completely (Translation p.6).

In regard to claim 23 and 52, Schrezenmeir et al disclose that the internal layer is compatible with the cells and/or enzymes (2) contained in the core, while the outside layer (6) is adapted to the surrounding medium (4) (Translation p.4, Fig. 1). Schrezenmeir et al teach that between both is a layer (7) variable from their structure (Translation p.4, Fig. 1). Schrezenmeir et al teach that variability is achieved by addition or removal of metal ions (Translation p.7). Because the layers have different functions and structures, they would be expected to necessary contain different components.

In regard to claims 28, 29, 57 and 58, it was well known in the art to have multiple layers in microcapsule covering to be ionically or covalently bonded. As evidenced by Schrezenmeir et al (DE4312970), who disclose "a microcapsule, in particular for insertion into tissue of living creatures or for biotechnological applications, having a preferably spherical core, containing living cells and/or enzymes, and a casing enclosing it", "the adjacent individual layers are covalently and/or electrostatically bonded together" (Abstract).

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 22, 24-27, 30-33, 44-51, 53-56, 59-62, and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu (4,659,662) in view of Schrezenmeir et al (DE 19519804).

Hsu discloses "ethanol and fermented beverages such as beer or wine are produced in a batch process by contacting a fermentable substrate with yeast cells encapsulated within a porous, semi-permeable material" (Abstract). Hsu discloses "yeast cells encapsulated within a porous, semi-permeable material" (Abstract). Hsu discloses that "the retaining means is permeable to the substrate and is substantially impermeable to the encapsulated yeast cells" (Abstract).

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Specifically in regard to claims 24, 25, 53 and 54, Hsu discloses that "preferably, the matrix encapsulating the yeast cells is an alginate gel" (Abstract). In regard to claim 25, 26, 54 and 55, Hsu discloses sodium alginate as a matrix material (Col.7 lines 48-49). In regard to claim 27 and 56, Hsu discloses "a liquid mixture of yeast cells and matrix material" (Col.7 lines 64-65).

In regard to claims 30, 31, 59 and 60, it is not clear what applicant means by "undesired reactant". However, Hsu discloses that "Desirably low levels of diacetyl and other unwanted compounds are attained in a relatively short time since the overall process reduces yeast growth and reproduction to a minimum. As a result, the production of undesired compounds such as acetaldehyde, hydrogen sulfide and the like, which are yeast-growth dependent and are responsible to a large degree for the "young" or "green beer" aroma, is greatly minimized. This in turn significantly reduces the time, otherwise required in conventional beer processes, of storage needed to reduce or eliminate such compounds. In addition to the foregoing, the present process enables the presence of substantial quantities of yeast (immobilized or encapsulated within the semi-permeable matrix material) during maturation; as a result, a rapid and high degree of reabsorption of diacetyl produced during fermentation and/or as a consequence of any yeast growth can be achieved" (Col. 4 lines 62-68, Col.5 lines 1-3).

In regard to claim 32 and 61, Hsu discloses use of yeast cells encapsulated within a porous, semi-permeable material in production of ethanol and fermented beverages such as wine or beer (Abstract). Hsu also discloses that "the essential feature of all beer production processes is the bringing together of yeast and brewers

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wort under conditions whereby carbohydrates (sugars) in the wort are converted to alcohol, with evolution of carbon dioxide" (Col.1 lines 32-35).

In regard to claim 33, 44, 62 and 73, Hsu discloses that "the particular strain of yeast employed can be selected from any of the known strains for beer or wine production, such as Saccharomyces cerevisiae or Saccharomyces uvarum, and is not per se critical with respect to the essential features of the present invention" (Col. 6 lines 55-60).

In regard to claim 45 and 74, Hsu disclose that "generally, the particles-comprised of yeast encapsulated within the matrix material--will be substantially
spherical in shape and will have an average diameter of from about 3 to about 5 mm"
(Col. 7 lines 25-29).

In regard to claim 50, Hsu disclose that "in wine fermentation, a concentrated grape juice recommended for the production of Riesling type wine was used" (Col. 14 lines 59-61).

In regard to claim 51, Hsu discloses that the invention relates to the production of fermented beverages such as beers and wines. Hsu also discloses that the term "wine" means an alcoholic beverage made by yeast fermentation of a must derived from fruits or berries, particularly grapes. As evidenced by Divies et al., it was known to perform secondary fermentation of wine to produce sparkling wine or champagne using encapsulated yeast.

In regard to claim 47, Hsu discloses "as shown in FIG. 2, the vessel 10 is a conventional vertical fermentation tank having a tapered bottom which communicates

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with an exit port protected by a screen or other filter device 18 sized so as to retain the yeast-containing particles 14 in the tank while permitting flow of fermented substrate to a subsequent processing step (e.g., stabilization, packaging) through line 20" (Col. 8 lines 63-67, Fig. 2).

In regard to claims 48 and 49, Hsu discloses that "the yeast-containing particles remaining in the vessel are then washed with cold water, buffered water or saline through a conventional jet spray before the next batch of new fermentation substrate is added to the vessel. In this manner, the yeast-containing particles can be continuously used until their fermentation and maturation efficiencies have decreased to a point where the fermentation/maturation can no longer be conducted within desirably short predetermined time limits" (Col. 13 lines 6-14).

Hsu does not disclose semipermeable multilayered capsule membrane.

Since Hsu teaches yeast cells encapsulated within a porous, semi-permeable material, and Schrezenmeir et al teach "bioactive capsule has a core which contains living cell and/or enzymes and a multilayered sheath which completely encloses the core", it would have been obvious to one skilled in the art at the time the invention was made to modify disclosure of Hsu and employ multilayered capsule structure disclosed by Schrezenmeir et al in order to achieve desired level of mechanical stability and different levels of layers permeability.

Claims 34, 36, 39-43 and 63, 65, 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu (4,659,662) in view of Schrezenmeir et al (DE 19519804)

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and further in view of Mansfeld et al (Coimmobilization of Yarrowia Lipolytica Cells and Invertase in Polyelectrolyte Complex Microcapsules).

Hsu and Schrezenmeir et al are taken as cited above.

In regard to claims 34, 36, 39-43 and 63, 65, 68-72, Mansfeld et al disclose various methods for coimmobilization of different enzymes, enzymes and microorganisms, or different microorganisms.

In gregard to claims 34 and 63, as evidenced by Divies et al. (US 5,627,062), it was known to use both lactic acid bacteria and mixture of yeast in fermentation processes (Col.1 lines 31-33).

In regard to claim 41-43 and 70-72, it was well known in the art to use different combination of polyanions and polycations in encapsulating materials. This is evidenced by Moo-Young et al. (U.S. 5,116,747), who describes the immobilization of cells and other biologically active materials within a semipermeable membrane or microcapsule composed of an anionic polymer such as alginate induced to gel in the presence of calcium and/or a polymeric polycation such as chitosan. It is also evidenced by Tsang et al (U.S. 4,663,286), who describes the encapsulation of solid core materials such as cells within a semipermeable membrane, by suspending the core material in a solution of a water-soluble polyanionic polymer, preferably alginate salts, forming droplets, and gelling the polyanion with a polyvalent polycation such as a polypeptide, a protein or a polyaminated polysaccharide, preferably polylysine, polyarginine, or polyornithine.

Mansfeld et al do not disclose semipermeable multilayered capsule membrane.



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Since Mansfeld et al disclose various methods for coimmobilization of different enzymes and /or different microorganisms in polyelectrolyte complex microcapsules, and Schrezenmeir et al teach "bioactive capsule has a core which contains living cell and/or enzymes and a multilayered sheath which completely encloses the core", it would have been obvious to one skilled in the art at the time the invention was made to modify disclosure of Mansfeld et al and employ multilayered capsule structure disclosed by Schrezenmeir et al in order to achieve desired level of mechanical stability and different levels of layers permeability. It would also have been obvious to vary capsules materials depending on the desired properties such as permeability, solubility and mechanical stability.

Claims 35, 37-38, 64, and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu (4,659,662) in view of Schrezenmeir et al (DE 19519804), Mansfeld et al (Coimmobilization of *Yarrowia Lipolytica* Cells and Invertase in Polyelectrolyte Complex Microcapsules) further in view of OKI DAIKICHI HONTEN (JP 56072686).

Hsu, Mansfeld et al and Schrezenmeir et al are taken as cited above.

Mansfeld et al and Schrezenmeir do not disclose glucose-fructose isomerases.

In regard to claim 36, 39, 40, 65, 68, and 69, Mansfeld et al also disclose coimmobilization of Yarrowia lypolitica cells and invertase in polyelectrolyte complex microcapsules (p.11).

OKI DAIKICHI HONTEN discloses application of glucose isomerase in production of sake, moromi and other wines (Abstract). OKI DAIKICHI HONTEN

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discloses that use of glucose isomerase in wine production results in improvement of their taste and flavor.

Since Mansfeld et al disclose various methods for coimmobilization of different enzymes and /or different microorganisms, Schrezenmeir et al teach bioactive capsule with a core containing living cell and/or enzymes and a multilayered sheath which completely encloses the core, and OKI DAIKICHI HONTEN discloses application of glucose isomerase in production of wines, it would have been obvious to one skilled in the art at the time the invention was made to modify disclosure of Mansfeld et al and enclose glucose isomerase and/or yeast in multilayered capsule structure disclosed by Schrezenmeir et al in order to achieve desired level of mechanical stability and different levels of layers permeability during and in order to improve wine taste and flavor.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Stulii whose telephone number is (571) 272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VS

KEITH HENDRICKS PRIMARY EXAMINER